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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,581	07/31/2003	Anne-Marie Rodriguez	0857/70669	5002
<div>7590 02/27/2007</div> <div>John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036</div>			<div>EXAMINER</div> <div>HAMA, JOANNE</div>	
			ART UNIT	PAPER NUMBER
			1632	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/632,581

Applicant(s)

RODRIGUEZ ET AL.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10,25-28 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) 11,12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10,25-28 and 48-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant filed a response to the Non-Final Action of May 22, 2006 on November 28, 2006. Claims 1-7, 9-12, 25-28, 48-54 are amended. Claims 8, 13-24, 29-47 are cancelled.

Claims 11, 12 remain withdrawn. See New/Maintained Rejections/Objections, below.

Claims 1-7, 9, 10, 25-28, 48-54 are under consideration.

Withdrawn Objections/Rejections

Specification

Applicant's arguments, see pages 10-11 of Applicant's response, filed November 28, 2006, with respect to the objection to the specification for missing SEQ ID NOs of sequences listed on page 29 have been fully considered and are persuasive. Applicant has provided an amendment to page 29, which includes SEQ ID NOs to the sequences. Applicant also indicates that the sequences on page 29 of the specification correspond to the sequences set forth in the Sequence Listing filed July 19, 2004. The objection to the specification has been withdrawn.

35 U.S.C. § 101

Applicant's arguments, see page 12 of Applicant's response, filed November 28, 2006, with respect to the rejection of claims 1-3, 49, 50, 53, 54 for being directed to non-statutory subject matter have been fully considered and are persuasive. Applicant has

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amended the claims such that the claimed cells are "isolated." The rejection of claims 1-3, 49, 50, 53, 54 has been withdrawn.

35 U.S.C. § 112, 2nd parag.

Applicant's arguments, see pages 12-13, filed November 28, 2006, with respect to the rejection of claims 1-3, 53, 54 as being indefinite for using the term "significant telomerase activity," have been fully considered and are persuasive. Applicant has indicated that the claims 1 and 53 have been amended to include the phrase, "of at least 20% to 50% of the telomerase activity of the HEK293T transformed cell line" to further describe "significant telomerase activity." The rejection of claims 1-3, 53, 54 has been withdrawn.

New/Maintained Objections/Rejections

Claim Objections

Claims 11, 12 remain objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 11, 12 have not been further treated on the merits. Claim 11 is a multiple dependent claim that depends on another multiple dependent claim, claim 9. Claim 12 is included in the objection because claim 12 depends on claim 11.

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It is noted that the objection to claims 4-7, 9, 10, 25-28, 48, 51, 52 are withdrawn as the claims are no longer multiple dependent claims depending from any other multiple dependent claim.

Claims 25-28, 48 are newly objected to because they depend on cancelled claims. Claim 25 depends on claim 13, a cancelled claim. Claims 26-28 are included in the objection because they indirectly depend on claim 13. Claim 48 depends on claim 25 and thus objected to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-28, 48 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 depends on claim 13, a cancelled claim. Since it is unclear what method is encompassed by claim 13, further examination of the claims cannot be carried out. Claims 26-28 indirectly depend on claim 13 and are thus included in the rejection. It is noted that claim 48 depends on claims 1 and 25. Because claim 25 depends on a cancelled claim, claim 48 has been interpreted to depend only on claim 1.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 49, 50, 53, 54 remain rejected and claims 4-7, 9-12, 48, 51, 52 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al., PCT

Publication No. WO 00/53795, publication date, September 14, 2000, previously cited, for reasons of record, May 22, 2006:

Applicant's arguments filed November 28, 2006 have been fully considered but they are not persuasive.

Applicant indicates that adipose-derived multipotent cells do not all necessarily and inherently possess the claimed characteristics as seen in the publication by Katz et al., 2005, Stem Cells, 23: 412-423 ("Katz II"). Applicant indicates that "Katz II" describes the isolation of multipotent populations of cells from adipose tissue using a method similar to that recited in WO 00/53795. The cells described in "Katz II" are MHC class I positive ("Katz II," page 416, right column, "HLA-ABC" and Table 4) and the cells are telomerase negative and ABCG2 negative ("Katz II," page 422, left column, and abstract). In response, the cells isolated in "Katz II" are different from those described in WO 00/53795 as WO 00/53795 indicates that the cells have telomerase activity (WO 00/53795, page 18, lines 8-9). While WO 00/53795 does not specifically indicate that the telomerase activity is at least 20% of that of HEK293T cells, it is presumed that the cells described in WO 00/53795 have this activity for reasons of inherency, unless

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demonstrated otherwise. Note that the cells in the specification and in WO 00/53795 are prepared in the same way and thus, it is presumed that the cells are the same.

Examiner's suggestion: Applicant may overcome the rejection by indicating method steps not taught by the WO document. Applicant is cautioned not to add new matter.

As such, the claims are rejected.

Claims 1-3, 49, 50, 53, 54 remain rejected and claims 4-7, 9-12, 48, 51, 52 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Zuk et al., 2001, Tissue Engineering, 7: 211-228, for reasons of record, May 22, 2006.

Applicant's arguments filed November 28, 2006 have been fully considered but they are not persuasive.

Applicant indicates that Zuk et al. do not anticipate the instant claims. As discussed in Applicant's argument regarding the art rejection of Katz et al., Applicant indicates that adipose-derived multipotent cells do not all necessarily and inherently possess the claimed characteristics. Applicant indicates that the method used in Zuk et al. is identical to that used in "Katz II," page 414, left column, line 10. Applicant indicates that the cells in "Katz II" do not have the same characteristics as those of the instant invention. In response, as discussed above in the Katz rejection, the cells described in WO 00/53795 have telomerase activity, while the cells in "Katz II" do not. Thus, the cells in "Katz II" are not the same as those in WO 00/53795. With regard to Applicant indicating that the method used in Zuk et al. is identical to that used in "Katz

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II," this argument is not persuasive because "Katz II" indicates that the method used to isolate the cells was a combination of that of Zuk et al., 2001 and Katz AJ.

Mesenchymal cell culture: adipose tissue. In Atala A, Lanza RP, eds. Methods of Tissue Engineering. Academic Press, NY: 2002: 277-286 (Katz II, page 414, left column, line 10). Subsequently, it cannot be concluded that the cells of Zuk et al. are necessarily the same as "Katz II," and thus different from that of the claims. Because the method steps described by WO 00/53795, Zuk et al., and the specification are the same and absent evidence to the contrary that Zuk et al.'s cell do not have any of the characteristics listed in claim 1, the cells of Zuk et al. anticipate the claims.

Applicant indicates that although the LPA cell population of Zuk et al. was shown to be capable of giving rise to different cell lineages, the population is heterogenous and contains endothelial cells, smooth muscle cells, and pericytes. On page 223 of Zuk et al., the apparent multipotent character may suggest the presence of a stem cell population but is not conclusive. Thus, the presence of multipotent cells cannot be concluded from Zuk et al. (Applicant's response, page 20). In response, while Zuk et al. was not certain whether their cultures contained multipotent cells, Zuk et al.'s 2002 publication (Zuk et al., 2002, Molecular Biology of the Cell, 13: 1059-1524 ("Zuk II")) and the teachings of the instant specification indicate that the Zuk et al., 2001 cultures did contain multipotent cells. This conclusion is based upon the fact that the method steps between Zuk, 2001, Zuk II, and the specification are the same. See MPEP 2112 which discusses that for reasons of inherency, something which is old does not become patentable upon the discovery of a new property and that an inherent feature need not

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be recognized at the time of the invention. The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

Applicant also indicates that the publication of Zuk II confirms the heterogenous nature of the LPA cell population and that it is critical to establish clonal populations before being able to conclude that the cells are multipotent stem cells (Applicant's response, pages 20-21). In response, this is not persuasive because as discussed in the previous paragraph, while Zuk et al., 2001 was not entirely certain that the cultures contained multipotent cells, Zuk et al.'s 2001 cultures contained multipotent cells as the method steps used to obtain the cells are the same as those described in Zuk II and the instant specification.

Applicant indicates that nothing in Zuk et al., 2001, teaches that the cells had any telomerase activity or were HLA Class I negative. Applicant indicates that the cells isolated using the method of Zuk et al. are seen to be HLA Class I positive and have no telomerase activity (this assertion being based upon the method of obtaining cells in Zuk et al. and Katz II being the same). With regard to the issue of self-renewal capacity

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of the PLA cells, Applicant indicates that Zuk et al., 2001 teach that the PLA population can be maintained in culture for 13 passages without losing its capacity to proliferate (Zuk et al., Figure 1B). 13 passages correspond to approximately 20 population doublings and not 130, as required in claim 1 (Applicant's response, pages 21-22). In response, while Zuk et al. teach 20 population doublings, nothing in Zuk et al. indicates that 20 population doublings is the limit of doublings that the PLA cells are capable of. That is, because Zuk et al. do not teach that cells either died or differentiated after 20 doublings, that an artisan cannot necessarily eliminate the possibility that the PLA cells are incapable of 130 doublings. As such, absent evidence to the contrary, the cells isolated by Zuk et al., 2001, are the same as those of the claimed invention.

Applicant indicates that Zuk et al., 2001 describe a process which is significantly different from that disclosed in the instant specification. In particular, Zuk et al. does not teach a step of selecting two subpopulations of cells: one having an adhesion rate of less than 12 hours and one having an adhesion rate of more than 12 hours. Further, there is no step of enriching the population that had an adhesion rate of more than 12 hours (Applicant's response, page 22). In response, while Zuk et al. do not specifically teach selection of two subpopulations of cells, the LPA cells taught by Zuk et al. comprise both populations as the cells described in Zuk et al. were plated and allowed to adhere overnight (Zuk et al., 2001, page 213, 1st parag.). Assuming that allowing the cells to settle overnight is from 5PM to 7AM the next morning (14 hours of incubation), both populations of cells would have been anticipated. While Zuk et al. were not aware

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of a population of cells that are adherent after 12 hours of plating, their culture contain these cells. As such, the claims remain anticipated.

As such, the claims remain rejected.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-

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272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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ANNE M. WEHBE, PH.D.
PRIMARY EXAMINER

